

### **REMARKS**

This submission is in response to the Office Action, mailed July 7, 2003. Applicants respectfully request entrance of the above claim amendments, presented in revised format. Applicants respectfully submit that the above claim amendments even more clearly bring the claims into a condition for allowance and, as such, are appropriate for an after-Final Office Action entrance into the application, in accordance with 37 C.F.R. § 1.116. No new matter is entered by the amendments. Basis for the amendments may be found, at least, in the specification at page 8, lines 3-15 and throughout the application as originally filed.

### **Rejections Under 35 U.S.C. § 112 ¶2**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

On page 4 of the Office Action the Examiner purports that claims 19-20 are indefinite as they “recite a method that fails to recite adequate methods steps.” More particularly, the Examiner purports that the only verb other than providing is the verb combining. Applicants are aware of no basis of law for a rejection of a method because it contain only one verb in the steps. Applicants maintain the claim is definite as written. Applicants note for example that such grounds of rejection is not set forth in MPEP §§ 2173.05(a)-(v), which lists specific topics where issues under 35 U.S.C. §112, second paragraph have been addressed. More specifically, the vaccine is provided with an adjuvant effect from the combination of the vaccine component with the claimed surfactants which have an overall HLB number between 5 and 15. Thus, the method which provides the adjuvant effect is the “combining” of the vaccine component (i.e. at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence) with the surfactant. Further, new claim 34 also recites the administration of the vaccine and recites “wherein said ethoxylated derivatives have an overall HLB number of between 5 and 15”.

The Examiner purports that claim 32 is similarly lacking in the proper recitation of steps. Applicants appreciate the Examiner’s suggestions and have added the step of “administering said vaccine to a subject.” It is believed this addresses the Examiner’s concerns. The rejection is therefore respectfully obviated.

Further on page 4, the Examiner purports that the claims are indefinite as “ the term ‘OE’ is vague and indefinite. Applicants are confused by this assertion by the Examiner as

this same rejection was addressed in Applicants November 4, 2002 response and Examiner withdrew this rejection. Applicants respectfully submit that the term “OE” is well known in the art as indicating ethoxylation as discussed in the articles which were provided.

Applicants respectfully request withdrawal of the rejection. In the event the Examiner does not withdraw the rejection, Applicants contend the present Office Action should have the status of non-final as this rejection constitutes a new grounds of rejection.

**Rejections under 35 U.S.C. § 102(b)**

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Initially, applicants respectfully request reconsideration of the rejection under 35 U.S.C. §102(b) as it is inconsistent with the election of species requirement set forth by the PTO in an earlier official action. More particularly, Applicants point out that the Examiner required an Election/Restriction on August 2, 2001 stating, “the methods are patentably distinct” and “the Inventions are patentably distinct” and that Applicants were required to elect a **specific** adjuvant, or a **specific** surfactant or a **specific** mixture of surfactants, such as those listed in the first table of Example 1 in the specification,...” [Emphasis in Original]. In response to the restriction requirement the applicants elected “composition H (Mannitan oleate (8 EO)) as the adjuvant, with traverse” stating that no undue burden was believed to be required due to the different species.

The Examiner has maintained the restriction requirement as restated in the present Office Action on page 2, paragraph 4 stating “[a]pplicant is advised that the application has been examined only as it recites the chosen species of ‘Composition h, mannitan oleate (8Eos);’”; however, the Examiner is citing references under 35 U.S.C. § 102(b) that utilize a non-elected mannitan oleate as allegedly rendering anticipated the claimed invention. The Examiner stated and maintained that the different adjuvants are patentably distinct that requires that other adjuvants of various ethoxylated indicies or lack thereof should not be used to render anticipated or obvious the current elected species since “patentably distinct” means both **novel and non-obvious**. Applicants request clarification from the Patent Office — if the Examiner continues to believe that previously identified adjuvants species are patentably distinct, then withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested. On the other hand, if the Examiner no longer believes that the rejection under 35 U.S.C. § 113(a) is proper, then withdrawal of the election requirement is respectfully requested.

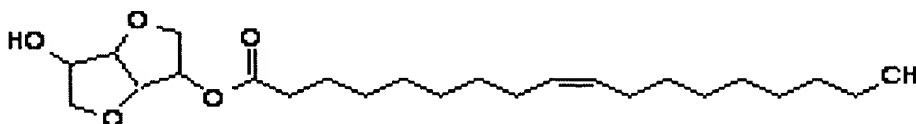
“Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). Applicants respectfully submit that none of the above references defines a method comprising the combination of a polyethoxylated mannitan oleate according to the claimed method. More specifically, it is respectfully submitted that the cited references do not teach the criticality of the recited polyethoxylated mannitan oleate.

Applicants provide further explanation as to why the new and amended claims even further define the invention over the applied prior art. With regard to the rejections in the Office Action, the Office Action purports that claims 19-20 and 30-32 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 3,678,149 (“the ‘149 Patent”). Specifically, the Examiner states that “the brief disclosure of the specification does not sufficiently distinguish the chosen species of mannitan oleate from the mannitan oleate of the references to render the instant ‘method’/‘process’ patentably distinct.” Further, the Examiner states “that ‘mannitan oleate’, such as that taught by the references, most likely comprises a number species of mannitan oleates, see O’Neill et al., (Table II, 1972).”

It is respectfully submitted that “most likely comprises” does not constitute anticipation. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. (*Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (PBAI 1987)). Rather, the Examiner is required to demonstrate each element of the claimed invention may be found in the cited reference. In the present case, the Examiner is required to demonstrate the reference discloses a *polyethoxylated* mannitan oleate with an EO indice of 8 along with the other claimed aspects of the invention.

The ‘149 patent recited the use of “purified mannide monooleate” and the Examiner cites to O’Neil Table II as showing that mannide oleates may contain any number of species. is ethoxylated. The mannide oleates of the Table II are for instance describing different alkyl chain lengths. However, there is no disclosure of polyethoxylates. A polyethoxylate has the general formula of:  $(\text{CH}_2\text{CH}_2\text{O})_n$ . Therefore, a polyethoxylated mannitan oleate of EO8 would contain eight  $(\text{CH}_2\text{CH}_2\text{O})_n$  in its backbone chain.

For example mannide monooleate ( $C_{24}-H_{42}-O_5$ ) is also known as mono-9-octadecenoate (similar to some species in Table II) and has the following structure:



This formula lacks even a single polyethoxylate as required by the claimed invention.

As Applicants previously stated the claimed invention does not involve mannitan oleate. Rather, the claimed invention involves *polyethoxylated* mannitan oleate. Therefore, the claimed invention is distinguished first (i) by the fact that *polyethoxylated* mannitan oleate is being utilized not mannitan oleate; second (ii) by the fact that due to the restriction requirement only the specific EO8 *polyethoxylated* mannitan oleate is under examination; and thirdly (iii) that the claimed compounds provide an HLB number between 5 and 15 as recited in the claim. Mannitan oleate is not polyethoxylated and does not provide the required HLB. In fact, mannitan oleate is one of the reference compounds utilized as a comparison to demonstrate the advantages and benefits of the claimed invention (See page 10, reference 2: mannitan oleate (HLB = 3.3)). Therefore, mannitan oleate is clearly outside the scope of the claimed subject matter whether the restriction requirement is maintained or not.

Additionally, Applicants respectfully submit these above arguments are not “attorney argument” rather they are specific argument directed to the physical properties of the claimed subject matter. Applicants respectfully request withdrawal of the rejection.

The Office Action states that claims 19-20 and 30-32 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Perlaza et al. (1998). Specifically, the Office Action purports that Perlaza et al. discloses mannitan oleate. As discussed with regard to the ‘149 Patent, the present invention is clearly distinguished and is not anticipated by a disclosure of mannitan oleate in vaccines. Applicants respectfully request withdrawal of the rejection.

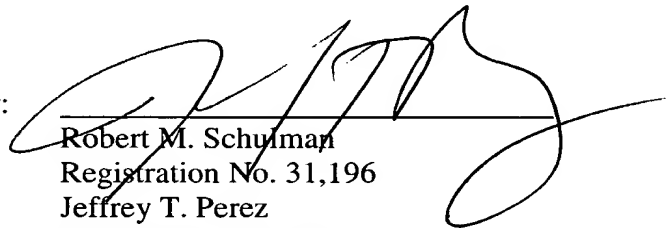
**Conclusion**

Applicants respectfully request an indication of allowance of all claims for the reasons set forth above. In the event that any issues remain outstanding in the application, Applicants would appreciate the courtesy of a telephone call to the undersigned counsel to resolve such issues in an expeditious manner and place the application in condition for allowance.

Respectfully submitted,

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